

# Becoming a Dexcom® CGM Trained Site

Dexcom G4® PLATINUM Professional Site Training Checklist



**Important:** The following information will be reviewed by a Dexcom employee or trained designee, with any healthcare facility or provider that chooses to train patients on the Dexcom G4 PLATINUM Professional CGM System. After the below information has been reviewed, the site will be considered trained.

Trained Site Name: \_\_\_\_\_

Site Representative Name(s): \_\_\_\_\_

Trained By: \_\_\_\_\_

Date of Training: \_\_\_\_\_

Receiver Serial Number: \_\_\_\_\_

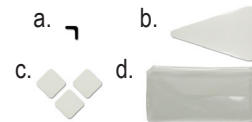
## ■ Step 1

### Review Dexcom G4 PLATINUM Professional System Indications for Use, Cleaning, Disinfection, Safety Information and Maintenance

- Review all indications, contraindications, warnings, and precautions (see the back side of this training checklist or the Dexcom G4 PLATINUM Professional System User's Guide)
- Review maintenance guidelines for the Dexcom G4 PLATINUM Professional System, including storage, cleaning and disinfection (see the Dexcom G4 PLATINUM Professional System User's Guide)



Dexcom G4® PLATINUM Receiver



- a. Acoustic spacer
- b. Triangular seal
- c. Square seals
- d. Receiver shield



Dexcom G4 PLATINUM Sensor and Applicator



Dexcom G4 PLATINUM Transmitter

## ■ Step 2

### Review Dexcom G4 PLATINUM Professional System Operations

- Charge receiver
- Proceed through initial Setup Wizard to set up time, date, transmitter ID and low/high glucose alert settings
- Review basic device training for each patient outlined by the Dexcom G4 PLATINUM Professional System Quick Start Guide
- Demonstrate proper device training    Date: \_\_\_\_\_
- Observe site doing device training    Date: \_\_\_\_\_

## ■ Step 3

### Review Dexcom STUDIO™ Software

- Install Dexcom STUDIO software
- Customize the Dexcom STUDIO software features and settings based on the HCP needs (Quick Print, Target Glucose, etc.)
- Review Dexcom blind and unblind feature and obtain unlock code to activate feature
- Review Dexcom CGM data interpretation and Dexcom STUDIO reports

## ■ Step 4

### Provide Dexcom G4 PLATINUM Professional System and Dexcom STUDIO Training Materials

- User's guide    • Quick start guide    • Dexcom STUDIO User's Guide
- Other products training materials as appropriate

## ■ Step 5

### Review Site Product Training Documentation

- Dexcom G4 PLATINUM Professional Site Training Verification Form and Checklist to be returned to Dexcom

## ■ Step 6

### Review of Dexcom Customer Operations and Technical Support

- Review how to contact Customer Operations at **1.877.339.2664** for patients who would like to purchase a personal Dexcom G4 PLATINUM CGM System
- Review how to contact Technical Support at **1.877.339.2664** 24/7
- Product troubleshooting guidelines can be found in the Dexcom G4 PLATINUM Professional System User's Guide

## ■ Step 7

### Review CGM Coding and Reimbursement

- Review current coding and reimbursement guidelines

# Becoming a Dexcom CGM Trained Site

## Dexcom G4 PLATINUM Professional Site Training Checklist

### Documentation of Site Training

- It is the responsibility of the Dexcom employee or designee to return documentation of each trained site, which includes:
  - Completed Dexcom G4 PLATINUM Professional Site Training Checklist
  - Completed Dexcom G4 PLATINUM Professional Site Training Verification Form
- Return BOTH documents to Dexcom via fax at **1.866.348.6030** OR e-mail at [fieldclinicaltraining@dexcom.com](mailto:fieldclinicaltraining@dexcom.com)
- For additional product support or training, see the Dexcom website at [www.dexcom.com](http://www.dexcom.com), contact your local Dexcom representative and/or Dexcom Technical Support at **1.877.339.2664**

### INDICATIONS FOR USE

The Dexcom G4 PLATINUM Professional Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons (**age 18 and older**) with diabetes. The system is intended for multiple patient use and requires purchase by a healthcare provider. The system is not intended for use in a hospital setting.

The Dexcom G4 PLATINUM Professional System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM Professional System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM Professional System results should be based on the trends and patterns seen with several sequential readings over time.

### IMPORTANT USER INFORMATION

Please review your product instructions before using your continuous glucose monitoring system. Indications, contraindications, warnings, precautions, cautions, and other important user information can be found in your product instructions. Discuss with your healthcare professional how you should use your sensor trend information to help manage your diabetes. Your product instructions contain important information on troubleshooting your system and on the performance characteristics of the device.

### CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The device is MR Unsafe. Do not bring any portion of the device into the MR environment. The Dexcom G4 PLATINUM Professional System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.
- Taking medications with acetaminophen (such as Tylenol®) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

### WARNINGS

- Thoroughly review the training materials included with your CGM system before using the Dexcom G4 PLATINUM Professional CGM System. Incorrect use might lead to you misunderstanding the information provided by your system, or might affect system performance, and you might miss a low or high blood glucose value.
- Do not use the Dexcom G4 PLATINUM Professional System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM Professional System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.
- Do not ignore symptoms of high and low glucose. If your sensor glucose readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range, so you do not miss a low or high blood glucose value.
- Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.
- Users need to adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007," <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.
- The transmitter should be cleaned and disinfected after use on each patient. This system may only be used for testing multiple patients when Standard Precautions and the manufacturer's cleaning and disinfection procedures are followed.
- Replace the receiver shield and acoustic spacer when transferring the receiver to a new patient. Wear gloves when handling the receiver. Handling the receiver without a shield or with a damaged shield could lead to contamination, which could cause infection.
- Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664** or **1.858.200.0200**.
- The Dexcom G4 PLATINUM Professional System is **not approved for use** in children or adolescents, pregnant women or persons on dialysis.
- It is not known how different conditions or medications common to the critically ill population may affect the

performance of the system. Therefore, the use of this system in the critically ill population is not recommended.

- Sensor placement and insertion is **not approved** for sites other than the belly (abdomen).
- Do not expect alerts from the Dexcom G4 PLATINUM Professional System until after the 2-hour startup. You will NOT get any sensor glucose readings or alerts until after the 2-hour startup ends AND you complete the startup calibration. During this time you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- If your transmitter or receiver case is damaged/cracked, do not use it. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.
- Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.
- Low/high glucose alerts and the 55 mg/dL low glucose alarm are all disabled when using the Dexcom G4 PLATINUM Professional System in blinded mode and will not alert you when the glucose is low or high. Check blood glucose meter if there are any signs or symptoms of low or high glucose.

### PRECAUTIONS

- Before opening the sensor package, wash your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.
- Before inserting the sensor, clean the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allow to dry. This may help prevent infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.
- Change the site where you place the sensor with each insertion, if the system is used multiple times. Using the same site too often might not allow the skin to heal, and might cause scarring or skin irritation.
- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor performance, and you might miss a low or high blood glucose value.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.
- To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising single arrow or double arrow, which indicates that your blood glucose is rising 2-3 mg/dL/min or more than 3 mg/dL/min. Also, do not calibrate when your receiver screen is showing the falling single arrow or double arrow, which indicates that your blood glucose is falling 2-3 mg/dL/min or more than 3 mg/dL/min. Calibrating during significant rise or fall of blood glucose may affect accuracy of sensor glucose readings.
- The system accuracy may be affected when your glucose is changing at a significant rate (e.g., 2-3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal. Since the system will not display your glucose rate of change in blinded mode, avoid calibrating after a meal or exercise.
- The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and you might miss a low or high blood glucose value.
- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life. When healthcare professionals use one transmitter for multiple patients, the transmitter must be returned to the healthcare professional.
- The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN®/SEVEN® PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also make sure to use the correct version of Dexcom STUDIO with your system.
- If all 3 square seals have been used before the end of the session, return the receiver to the healthcare professional office. Do not charge the receiver if you cannot seal it. Unsealed receivers could spread contamination.
- Do not puncture the receiver shield for any reason. Punctured shields could spread contamination.
- Return the receiver to the healthcare professional if the acoustic spacer moves away from the upper right corner. The entire receiver shield must be discarded and replaced. The spacer allows the receiver speaker to work properly when the shield is in place. If the spacer moves and the receiver speaker volume is low, you might miss alerts or alarms.
- Inspect the receiver shield, seals and spacer for tears or other damage or defects before you place the components on the receiver. Do not use any parts of the receiver shield pack that are damaged or defective. If the receiver shield, seals and spacer are torn, damaged or otherwise defective after giving to the patient, the patient should return the receiver to the healthcare professional for a replacement. The damaged or defective receiver shield should not be taken off by the patient. If a defect or malfunction is suspected, the healthcare professional should retain the shield and contact Dexcom Technical Support. The shield helps protect the user and healthcare professionals from contamination and allows the receiver to function properly.

### CAUTION

U.S. (Federal) law restricts the sale of the Dexcom G4 PLATINUM Professional System to sale by or on order of a physician.

**Dexcom®**  
One Step Ahead



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Technical Support: **1.877.339.2664 / 1.858.200.0200** | [www.dexcom.com](http://www.dexcom.com)

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